DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6546. Various drugs. (Inj. No. 335.)

COMPLAINT FOR INJUNCTION FILED: 6–24–58, N. Dist. N.Y., against Delmar Pharmacal Corp., Rensselaer, N.Y.

NATURE OF BUSINESS: The defendant was engaged in manufacturing, preparing, packing, selling, and distributing directly in interstate commerce, and delivering to the Rand Pharmaceutical Co., Inc., and Previcol, Inc., Rensselaer, N.Y., for sale and distribution in interstate commerce, various articles of drug.

CHARGE: The complaint alleged that the defendant was introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce, various articles of drug which were adulterated and misbranded in the following respects:

(a) A number of articles of drug were adulterated within the meaning of 501(b), in that said articles purported to be drugs, the names of which were recognized in an official compendium, the U.S. Pharmacopoeia, and their strength differed from the standards set forth in such compendium;

(b) A number of articles of drug were adulterated within the meaning of 501(c), in that they were not subject to the provisions of 501(b) and their strength differed from, and their quality fell below, that which they purported and were represented to possess;

(c) A number of articles of drug were misbranded within the meaning of 502(a), because of false and misleading statements in the labeling of said articles with respect to the nature and quantity of the ingredients;

(d) A number of articles of drug were misbranded within the meaning of 502(d), in that they were drugs for use by man and they contained a quantity of narcotic or hypnotic substance, or a chemical derivative of such substance, which derivative had been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming, and their labels failed to bear the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming";

(e) A number of articles of drug were misbranded within the meaning of 502(e)(2), in that they were drugs not designated solely by a name recognized in an official compendium and they were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient;

(f) A number of articles of drug were misbranded within the meaning of 502(f)(1), because their labeling failed to bear adequate directions for use in that the recommended or usual dose was omitted; and

(g) A number of articles of drug were misbranded within the meaning of 503(b)(4), in that they were drugs within the meaning of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The complaint alleged further that the adulterated and misbranded condition of said articles of drug resulted from deficiencies in the ingredients of said articles, or the presence in said articles of drug of ingredients in amounts in excess of those declared on the labels, which were due to inadequate manufacturing facilities, lack of identification control, lack of adequate analysis and formulas, or lack of other precautions essential to the compounding of potent